

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG**

BOEHRINGER INGELHEIM)	
PHARMACEUTICALS INC.,)	
BOEHRINGER INGELHEIM)	
INTERNATIONAL GMBH,)	
BOEHRINGER INGELHEIM)	
CORPORATION and BOEHRINGER)	Case No.: 1:20-cv-19 (TSK) (Lead)
INGELHEIM PHARMA GMBH & CO.)	
KG,)	<i>Consolidated with</i>
)	Case No.: 1:20-cv-90
Plaintiffs,)	Case No.: 1:24-cv-82
)	
v.)	REDACTED -
)	PUBLIC VERSION
MYLAN PHARMACEUTICALS, INC.,)	
MYLAN INC., MYLAN LABORATORIES)	
LIMITED,)	
Defendants.		

PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

The sole claim construction dispute before this Court concerns the proper construction of “corn starch” in U.S. Patent No. 11,033,552 (the “‘552 Patent”). *See Ex. 1* (‘552 Patent).

Boehringer proposes the term’s plain and ordinary meaning—starch made from corn. This construction follows the basic principle that claim terms “are generally given their ordinary and customary meaning.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The patent offers no alternative definition, and all extrinsic and scientific references consistently define corn starch as starch derived from corn.

Mylan’s proposed construction, however, fails at the most basic level—it simply repeats “corn starch” and does not define the term at all. Instead of offering a definition, Mylan asks this Court to carve out an exception: corn starch should not count as “corn starch” when it appears alongside pregelatinized starch. This distinction lacks support in the patent itself, in established patent law, or even in pharmaceutical science. It creates an arbitrary limitation that resembles arguing that flour is not “flour” when it is part of a cake mix rather than measured from the bag.

Mylan appears to be crafting this exception solely in an attempt to avoid infringement—an approach that Federal Circuit precedent explicitly prohibits because it distorts claim construction from an objective analysis of patent language into a results-oriented exercise. It is well-established that “[a] ‘claim is construed in the light of the claim language . . . not in light of the accused device.’” *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1367 (Fed. Cir. 2008) (quoting *Exigent Tech., Inc. v. Atrana Solutions, Inc.*, 442 F.3d 1301, 1310 n. 10 (Fed. Cir. 2006)).

The Court should adopt Boehringer’s straightforward construction that respects the term’s ordinary and plain meaning as understood by persons skilled in the art.

II. BACKGROUND

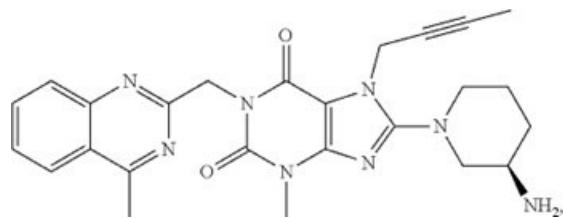
A. Background of the '552 Patent

The '552 Patent covers specific pharmaceutical compositions for linagliptin, a dipeptidyl peptidase IV (DPP-IV) inhibitor developed by Boehringer. Linagliptin is the sole active ingredient of Boehringer's TRADJENTA® product, a medication for treating type 2 diabetes. *See* Ex. 2 (TRADJENTA® label) at BILIN00713856, 870. Mylan now seeks FDA approval for a generic version of this treatment.

Developing a stable linagliptin formulation presented significant challenges. Linagliptin can degrade under certain conditions, including through reactions with other components, which required Boehringer to spend significant resources to develop a stable composition that is both effective and commercially viable. *See, e.g.*, Ex. 1 ('552 Patent) at 1:24–45. This work resulted in the '552 Patent.

The '552 Patent has one independent claim (claim 1):

1. A solid-form pharmaceutical composition comprising as an active ingredient 5 mg of a DPP IV inhibitor compound of formula



or a salt thereof, a first diluent, a second diluent, a binder, a disintegrant and a lubricant, wherein the first diluent is mannitol, the second diluent is pregelatinized starch, the binder is copovidone, the disintegrant is corn starch, and the lubricant is magnesium stearate; and wherein the DPP IV inhibitor compound is present in an amount 0.5-7.0% based on the total weight of DPP IV inhibitor compound, first diluent, second diluent, binder, disintegrant and lubricant.

Id., claim 1. This patent covers the formulation used in Boehringer's TRADJENTA® product, which Mylan now seeks FDA approval to produce as a generic medication.

B. Background of the Technology

Pharmaceutical compositions combine active pharmaceutical ingredients with carefully selected excipients to create effective medications. *See Ex. 3* (Nikita N. Bagal et al., *A Review On Excipient Used In Preparation / Formulation of Solid Dosage Form*, 2 Int. J. of Pharm. Sci. 1711 (2024) (“Bagal”)) at 1711. Excipients are non-active substances added to a composition for a variety of purposes, including to enhance stability, dosage, bioavailability, and overall performance of the composition. *Id.*; *Ex. 4* (Giorgio Piffer & Patrizia Restani, *The Safety of Pharmaceutical Excipients*, 58 Il Farmaco 541 (2002)) at 541.

Although excipients may be classified by their primary function—as binders, disintegrants, or diluents—some excipients can serve multiple roles simultaneously in a pharmaceutical formulation. *Ex. 3* (Bagal) at 1711. Binders, for example, may be used to help hold together the individual components of a pharmaceutical composition. *Id.* Disintegrants may be used to aid in the breakdown of tablets into smaller particles when the tablets are exposed to the fluid in the gastrointestinal tract upon administration, aiding in the dissolution and absorption of active pharmaceutical ingredients in the human body. *Id.* Fillers, or diluents, may be used to bulk up a composition to ensure accurate dosage measurements. *Id.*

Corn starch, as the name suggests, is starch made from corn. *Ex. 5* (Corn Starch, Drugs.com, available at <https://www.drugs.com/inactive/corn-starch-30.html>). It consists of two polymers, amylose and amylopectin, in a crystalline structure. *See Ex. 6* (Barmi Hartesi, et. al., *Starch as Pharmaceutical Excipient*, 41 Int. J. Pharm. Sci. Rev. Res. 59 (2016), available at <https://globalresearchonline.net/journalcontents/v41-2/14.pdf> (“Hartesi”)) at 59. Depending on how it is used, corn starch may be suitable for a number of different pharmaceutical applications, including as a binder, diluent, and/or disintegrant. *Ex. 7* (Handbook of Pharmaceutical Excipients

(5th Ed.) (excerpted) (“HPE”))¹ at 725; Ex. 8 (Jacques Michaud, Starch Based Excipients for Pharmaceutical Tablets, Pharmaceuticals (June 2002), available at <https://www.pharmaexcipients.com/wp-content/uploads/2020/11/Starch-based-excipients-for-pharmaceutical-tablets.pdf>) at 42.

Pregelatinized starch is a modified starch that is created by disrupting the bonds between starch polymers through a process called gelatinization. See Ex. 9 (*Pregelatinized Maize Starch in Pharmaceuticals: A Guide*, Colorcon (July 2, 2024), available at <https://www.colorcon.com/education-insights/pregelatinized-maize-starch-in-pharmaceuticals-a-guide> (“Colorcon Guide”)) at 1; Ex. 7 (HPE) at 731. This modification can be full or partial. Fully pregelatinized starch has full binding capabilities but lesser disintegrant capabilities. See Ex. 9 (Colorcon Guide) at 1; Ex. 10 (Bytul M Rahman, et al., *Effect of Starch 1500 as a Binder and Disintegrant in Lanivudine Tablets Prepared by High Shear Wet Granulation*, 21 Pakistan J. of Pharm. Sci. 455 (Oct. 2008), available at <https://pubmed.ncbi.nlm.nih.gov/18930870/> (“Rahman”)) at 455; Ex. 11 (Charles R. Cunningham, *Starch Contrasts*, Excipient Focus (“Cunningham”)) at COLORCON0030. Partially pregelatinized starch undergoes limited modification, such that only a portion of the bonds are disrupted. See Ex. 9 (Colorcon Guide) at 1. Partially pregelatinized starch thus contains both pregelatinized starch fractions and unmodified, native starch fractions. *Id.*; Ex. 11 (Cunningham) at COLORCON0030. This provides partially pregelatinized starch with the functions of both native corn starch and pregelatinized starch simultaneously. Ex. 9 (Colorcon Guide) at 1; Ex. 10 (Rahman) at 455; Ex. 11 (Cunningham) at COLORCON0030; Ex. 6 (Hartesi) at 63.

¹ Mylan cites to other pages in Handbook of Pharmaceutical Excipients (5th Ed.) as supporting intrinsic evidence for its construction for “corn starch.”

C. Person of Ordinary Skill in the Art (“POSA”)

The person of ordinary skill in the art (“POSA”) for the ’552 Patent would be a person with an advanced degree in the pertinent field, such as pharmacology, pharmaceutics, medicinal chemistry, clinical research science, and medicine. To the extent a person does not have the necessary expertise in all disciplines, he or she would work with another person or with a team of persons with the necessary experience or expertise.

D. Background of the Present Action

Boehringer asserts that Mylan infringes claims 1, 2, 4, and 6–16 of the ’552 Patent. The formulation of Mylan’s generic ANDA product includes [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]

[REDACTED]

[REDACTED] at 1. [REDACTED]

[REDACTED]

[REDACTED] Ex. 9 (Colorcon Guide) at 1; Ex. 10 (Rahman) at 455.

In an attempt to avoid infringement, Mylan seeks a construction of “corn starch” that is contrary to its plain and ordinary meaning. Its position contains a clear contradiction—on the one hand, Mylan admits that [REDACTED]

See Ex. 13 (Mylan’s Final Invalidity Contentions (excerpted)) at 135–36 (contending that [REDACTED]

[REDACTED]

[REDACTED]). Mylan likewise does not dispute that [REDACTED] *Id.* at 135–40; *see*

also Ex. 14 (Mylan’s Noninfringement Contentions (excerpted)) at 12–13.

Yet, on the other hand, Mylan contends that when this same [REDACTED]
[REDACTED], it stops being “corn starch” for purposes of the ’552 Patent.

See id. This position appears designed solely to argue that its product [REDACTED]

[REDACTED] *Id.*²

III. LEGAL STANDARDS

Claim construction starts with the words of the claims themselves, which “are generally given their ordinary and customary meaning” as would have been understood by a person of ordinary skill in the art at the time of the invention and which can “provide substantial guidance as to the meaning of particular claim terms.” *Phillips*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). “[T]he claim construction process is not aimed at assuaging parties’ concerns about opposing parties’ litigation tactics.” *Am. River Nutrition, LLC v. Beijing Gingko Grp. Biological Tech. Co.*, 419 F. Supp. 3d 1226, 1232 (C.D. Cal. 2020). Rather, “[a] claim is construed in the light of the claim language, the other claims, the prior art, the prosecution history, and the specification, **not** in light of the accused device.” *SRI Int’l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1118 (Fed. Cir. 1985) (emphasis in original).

The ordinary and customary meaning understood by a POSA provides the “objective baseline” for the claim’s construction. *Phillips*, 415 F.3d at 1313. Thus, the claim language itself is first and foremost in importance when construing the meaning and scope of the patent. *See Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999). “General descriptive terms will ordinarily be given their full meaning; modifiers will not be added to broad terms standing alone.” *Id.* “In short, a court must presume that the terms in the claim mean what

² For the avoidance of doubt, Boehringer asserts that Mylan literally infringes claim 1 of the ’552 Patent under either parties’ proposed construction.

they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms.” *Id.* Indeed, as the *Phillips* court instructed, “[i]n some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” 415 F.3d at 1314.

“[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Id.* at 1316. “[E]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted). “Absent disclaimer or lexicography, the plain meaning of the claim controls.” *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1369 (Fed. Cir. 2012); *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014) (“[T]he specification and prosecution history only compel departure from the plain meaning in two instances: lexicography and disavowal.”); *see also DSW, Inc. v. Shoe Pavilion, Inc.*, 537 F.3d 1342, 1347 (Fed. Cir. 2008) (“[A]bsent contravening evidence from the specification or prosecution history, plain and unambiguous claim language controls the construction analysis.”). “The standards for finding lexicography and disavowal are exacting” and require a patentee “‘clearly set forth a definition of the disputed claim term’ other than its plain and ordinary meaning. . . . [T]he patentee must ‘clearly express an intent’ to redefine the term.” *GE Lighting Sols.*, 750 F.3d at 1309 (quoting *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)). Likewise, disavowal

“requires that the specification or prosecution history make clear that the invention does not include a particular feature.” *GE Lighting Sols.*, 750 F.3d at 1309 (cleaned up). “To constitute disclaimer, there must be a clear and unmistakable disclaimer.” *Thorner*, 669 F.3d at 1366–67.

IV. CONSTRUCTION OF THE TERM “CORN STARCH” IN THE ’552 PATENT

The term “corn starch” appears in claim 1 of the ’552 Patent. The parties’ proposed constructions are below:

Boehringer’s Proposed Construction	Mylan’s Proposed Construction
Plain and ordinary meaning, that is, starch made from corn	“corn starch, which is an additional, distinct ingredient from pregelatinized starch (including any unmodified starch present therein)”

There is no real dispute about what “corn starch” means. Boehringer proposes the plain and ordinary meaning: “starch made from corn.” Mylan begins its construction by simply repeating “corn starch” without defining it. When a party defines a term by simply restating it, they concede that the term’s meaning is self-evident. *See Cinsay, Inc. v. Joyus, Inc.*, No. 13 Civ. 03628, 2015 WL 1002990, at *12 (N.D. Tex. Mar. 4, 2015) (“The Court notes that Joyus simpl[y] repeats the terms ‘transmitting’ in its proposed constructions of these phrases. . . . This indicates that Joyus does not actually dispute use of the plain and ordinary meaning of . . . these terms.”). This should end the matter. As the Federal Circuit established in *Phillips*, readily understandable claim terms should be given their plain and ordinary meaning. 415 F.3d at 1314.

The only actual dispute involves Mylan’s attempt to argue that Boehringer disclaimed claim scope such that “corn starch” excludes corn starch when it appears alongside pregelatinized starch—even though corn starch remains corn starch regardless of what surrounds it. Under established patent law, however, there can be no such disclaimer without “clear and unmistakable” evidence—which is entirely absent here. *See Thorner*, 669 F.3d at 1366–67. Nor does Mylan’s

construction find support in the claim’s language, specification, prosecution history, or extrinsic evidence. Nothing suggests corn starch should be defined based on its surrounding ingredients.

The Court should reject Mylan’s litigation-driven construction that deviates from the plain and ordinary meaning.

A. Boehringer’s Proposed Construction Is the Ordinary and Customary Meaning

Where a patent uses a term in its everyday meaning and the “written description and prosecution history do not provide additional information as to the parameters” of the term, it is appropriate to give a term “ordinary usage.” *3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1333–34 (Fed. Cir. 2013). As the Federal Circuit noted in *Phillips*, at times “the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Phillips*, 415 F.3d at 1314. Such is the case here.

“Corn starch” has a meaning so clear that even non-scientists understand it: starch made from corn. This definition appears consistently across a broad spectrum of sources. See, e.g., Ex. 15 (*cornstarch*, Merriam-Webster Dictionary (11th Ed. 2020), available at <https://www.merriam-webster.com/dictionary/cornstarch> (last visit May 8, 2025)) (“starch made from corn . . .”); Ex. 16 (*cornstarch*, Collins Dictionary, available at <https://www.collinsdictionary.com/us/dictionary/english/cornstarch> (last visited May 8, 2025)) (“a fine white powder made from corn . . .”); Ex. 17 (*cornstarch*, Cambridge Dictionary, available at <https://dictionary.cambridge.org/us/dictionary/english/cornstarch> (last visited May 8, 2025)) (“a white flour made from corn . . .”); Ex. 18 (United States Pharmacopeia (2006 Ed.)) at 3436 (describing “corn starch” as “consist[ing] of the starch granules separated from mature grain of

corn”); Ex. 19 (Remington: Essentials of Pharmaceuticals) at 1090 (“Starch . . . consists of the granules separated from the mature grain or corn . . .”).

The ’552 Patent uses “corn starch” in this same ordinary way throughout the specification and claims without defining it. Claim 1 simply states “the disintegrant is corn starch.” Ex. 1 (’552 Patent), claim 1. The specification mentions corn starch among suitable disintegrants, *id.* at 2:16–20, and describes how a pharmaceutical composition may be made using corn starch, among some examples, *id.* at 8:67–9:3 (“An active DDP IV inhibitor ingredient with a primary amino group, mannitol, pregelatinized starch and corn starch are blended in a suitable mixer to produce the pre-mix.”). Although the patent uses the term “corn starch” repeatedly, it never provides any definition—certainly not the specialized limitation that Mylan now proposes. This absence of definition reinforces that the term’s meaning is self-evident.

Similarly, the prosecution history uses “corn starch” in its conventional sense without special explanation. For example, the examiner noted that the prior art teaches “a pharmaceutical composition . . . wherein . . . a disintegrant can be corn starch,” and referred to replacing “corn starch with a combination of crospovidone and corn starch as disintegrants.,” Ex. 21 (File History of the ’552 Patent (excerpted)), 1/23/2020 Non-Final Rejection, at 4–5, 9–10. As the Federal Circuit held in *InterDigital Communications*, courts should construe terms with their ordinary meaning when “[n]either the specification nor the prosecution history contains a restrictive definition” and “the patentee did not at any point disavow the broader interpretation.” *InterDigital Commc’ns, LLC v. Int’l Trade Comm’n*, 690 F.3d 1318, 1324 (Fed. Cir. 2012). That is the case here: the term’s consistent usage without special definition throughout the intrinsic record supports applying the plain and ordinary meaning. *See also Mirror Worlds Techs., LLC v. Meta Platforms, Inc.*, 122 F.4th 860, 872 (Fed. Cir. 2024) (“The broad claim language, ‘data unit,’ does not suggest

any such limitation. And neither does the rest of the intrinsic evidence, which nowhere limits data units to information ‘of direct user interest’ or an equivalent expression.”).

B. Mylan’s Proposed Construction Has No Basis in the Intrinsic Record and Contravenes Established Canons of Claim Construction

There is no genuine dispute about what corn starch means. Mylan itself uses the term in its construction without defining it. This circular approach—defining a term by restating the term itself—confirms that no genuine definition is needed.

At bottom, the real dispute boils down to whether Mylan can properly add an exception to this plain term: “which is an additional distinct ingredient from pregelatinized starch (including any unmodified starch present therein).” This additional language does not define what corn starch is, but instead creates an exclusion that contradicts the term’s established meaning. Under Mylan’s construction, if corn starch is “present therein” with pregelatinized starch, it would no longer count as corn starch.

The motivation behind Mylan’s unusual construction is clear. Mylan intends to manufacture its proposed generic ANDA product using [REDACTED]

[REDACTED]
[REDACTED] *see also supra* § II.D. [REDACTED]

[REDACTED] *See Ex. 14 (Mylan’s Noninfringement Contentions (excerpted)) at 12–13; supra* § II.D; *see also* Ex. 13 (Mylan’s Final Invalidity Contentions (excerpted)) at 135–36. With this non-infringement strategy in mind, Mylan asks the Court to construe “corn starch” to exclude any “unmodified starch present therein,” *even when* the unmodified starch is corn starch. This approach should be rejected as an improper attempt to define a patent term based on the accused product, which is prohibited. *See SRI Int’l*, 775 F.2d at 1118 (a

“claim is construed in the light of the claim language, the other claims, the prior art, the prosecution history, and the specification, not in light of the accused device”); *see also NeoMagic Corp. v. Trident Microsystems, Inc.*, 287 F.3d 1062, 1074 (Fed. Cir. 2002) (“It is well settled that claims may not be construed by reference to the accused device.”).

Mylan’s proposed construction should also be rejected for at least two additional reasons: it imports a disclaimer despite no evidence of lexicography or disavowal in the intrinsic record and it improperly seeks to construe “corn starch” based on how it is added to the pharmaceutical composition, not on whether it is present.

First, under Federal Circuit law, “the specification and prosecution history only compel departure from the plain meaning in two instances: lexicography and disavowal.” *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014) (citing *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)). Mylan cannot show either.

“The standards for finding lexicography and disavowal are *exacting*.” *Id.* (emphasis added). For a patentee to act as its own lexicographer, it “must ‘clearly set forth a definition of the disputed claim term’ other than its plain and ordinary meaning. It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must ‘clearly express an intent’ to redefine the term.” *Thorner*, 669 F.3d at 1365 (internal citation omitted). Similarly, disavowal “requires that the specification or prosecution history make clear that the invention does not include a particular feature.” *GE Lighting Sols.*, 750 F.3d at 1309 (cleaned up). “It is [] not enough that the only embodiments, or all of the embodiments, contain a particular limitation. . . . To constitute disclaimer, there must be a clear and unmistakable disclaimer.” *Thorner*, 669 F.3d at 1366–67.

There is no evidence of any lexicography or disavowal here, let alone the “clear” intent required to satisfy this “exacting” standard. *See GE Lighting Sols.*, 750 F.3d at 1309. Nothing in the intrinsic record “clearly set[s] forth a definition of” “corn starch” or rises to a “clear and unmistakable disclaimer” of the full scope of “corn starch.” *Thorner*, 669 F.3d at 1365, 1367. The ’552 Patent nowhere excludes “any unmodified starch present” in pregelatinized starch from being considered corn starch. Instead, it consistently uses the term “corn starch” according to its plainly understood meaning. *See supra* § IV.A. The same is true for the term’s use throughout the ’552 Patent prosecution history. *See id.* Thus, nothing in the intrinsic record suggests corn starch should be defined differently when it appears alongside pregelatinized starch. This is particularly significant because partially pregelatinized corn starch comprises both pregelatinized corn starch and unmodified corn starch fractions—a scientific fact not disputed by either party.

The simple fact that the ’552 Patent lists both “corn starch” and “pregelatinized starch” does not constitute a “clear and unmistakable disclaimer” that would exclude corn starch fractions present in partially pregelatinized starch from the meaning of “corn starch.” *See Ring Plus, Inc. v. Cingular Wireless Corp.*, 614 F.3d 1364–65 (Fed. Cir. 2010) (rejecting narrowing construction of an “ordinary term with a plain meaning” where defendant “fail[ed] to identify any portion of the specification that limits the claimed [term] to . . . a specific time period.”). Even if separately listing “corn starch” and “pregelatinized starch” was considered a limitation in some embodiments, the Federal Circuit has repeatedly warned against importing limitations from specific embodiments into claim terms used in their general sense. In *Phillips*, the court rejected a construction that would have limited “baffles” to only “steel baffles,” emphasizing that such narrowing contradicted the term’s ordinary meaning. 415 F.3d at 1314. Similarly, in *Automed Techs. v. Microfil, LLC*, the Federal Circuit refused a narrowing construction that would “fly in the face of the specification

and would engraft onto the claims an unwarranted limitation.” 244 F. App’x 354, 357 (Fed. Cir. 2007). The principle applies perfectly here: when “[n]othing in the patent’s claims or written description [or prosecution history] suggests a departure from the disputed term’s ordinary meaning,” courts reject attempts to narrow that meaning. *Zenith Elecs. Corp. v. PDI Commc’n Sys., Inc.*, 522 F.3d 1348, 1356 (Fed. Cir. 2008)

Second, Mylan’s proposed construction defies common sense and potentially renders the claim incomprehensible, making it improper. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 258 F.3d 1317, 1324 (Fed. Cir. 2001) (“If an argument offered in support of a particular claim construction is so convoluted and artificial that it would not be apparent to a skilled artisan reading the patent and the prosecution history, the argument is simply unhelpful to the performance of our task.”). Corn starch is corn starch, regardless of how it enters the pharmaceutical composition. The nature of corn starch does not change based on whether it was added as a pure ingredient or as part of partially pregelatinized starch. This is straightforward science—corn starch does not know its own history. [REDACTED]

[REDACTED] In both instances, it is “corn starch.”

The ’552 Patent simply claims what ingredients are present in the pharmaceutical composition, not how those ingredients got there. Any attempt to argue otherwise is contrary to Federal Circuit law and should be rejected. *See Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1558 (Fed. Cir. 1995) (“Under the proper charge, the jury would not have been asked if Lubrizol used Exxon’s starting ingredients. Instead, the jury would have been asked to find whether Exxon had proved by a preponderance of the evidence that Lubrizol’s products at some time contained each of the claimed recipe ingredients in the amounts specifically claimed.”); *see also PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1245 (Fed. Cir. 2002) (construing “the

term ‘composition’ . . . to mean a physical mixture” and noting that it “may be a pre-mixture, *i.e.*, a mixture that comes into being well before being used for sprout suppression, or a mixture that is formed at any time during use, such as through simultaneous application of the constituent chemicals, as long as a mixture is indeed formed.”); *Mars, Inc. v. H.J. Heinz Co., L.P.*, 377 F.3d 1369, 1375 (Fed. Cir. 2004) (holding that “the term ‘ingredients’ in the phrase ‘a mixture of solid and lipid ingredients’” is **not** limited “only to starting materials” and instead the phrase “refers to the components of the inner component ‘at any time from the moment at which the ingredients are mixed together.’”). Nowhere does the patent specify a particular method for introducing corn starch into the formulation. What matters is that corn starch is present in the final product, not how it was added.

Any attempt to limit “corn starch” based on its source rather than its identity contradicts both scientific reality and patent law principles. The Court should reject this artificial distinction and recognize that corn starch is corn starch, regardless of its origin or how it was introduced into the formulation.

V. CONCLUSION

For the foregoing reasons, Boehringer respectfully requests that the Court adopt Boehringer’s proposed construction of “corn starch.”

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